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O'Shea Getz P.C. 1500 MAIN ST. SUITE 912 SPRINGFIELD, MA 01115				
EXAMINER				
HAMMOND, CHARLES				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/599,695

Applicant(s)

WARDLAW, STEPHEN C.

Examiner

Charles D. Hammond

Art Unit

4172

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 13-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/88)
Paper No(s)/Mail Date See Continuation Sheet
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

Continuation of Attachment(s) 3. Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :10/05/2006; 4/25/2007; 6/10/2009; 6/22/2009.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-12 and 33, drawn to an apparatus for analyzing biological fluid.

Group II, claim(s) 13-21 drawn to an apparatus for analyzing biological fluid.

Group III, claim(s) 22-26 drawn to an apparatus for analyzing biological fluid.

Group IV, claim(s) 27-31 drawn to a method of enumerating the cellular particulate constituents of a sample of whole, anti-coagulated blood.

Group V, claim(s) 32 drawn to a method of enumerating the cellular or particulate constituents of whole, anti-coagulated blood.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The inventions identified as Groups I-V each share a common technical feature, which is an apparatus comprising a first and second planar member wherein at least one of the planar members is transparent, at least three separators disposed between the planar members, and wherein at least one of the first planar member, second planar member, or separators is sufficiently deformable.

However, the shared technical feature is well known in the art at the time of the invention. Austin et al. (U.S. Patent No. 6,632,652) teaches an apparatus for sorting

particles in a liquid sample comprising the limitations set forth above. Austin teaches an apparatus (80) comprising a first planar member (26), a second planar member (88), wherein at least on the first planar member and second planar member is transparent, at least three separators (62) disposed between the planar members, and wherein at least one of the first planar member, second planar member, or separators is sufficiently deformable (see column 9 lines 29-67, column 10 lines 1-22, and Fig. 7). Since the technical feature does not contribute over the prior art, Groups I-V do not relate to a single general inventive concept.

3. During a telephone conversation with Mr. Richard Getz on September 16th, 2009 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-12 and 33. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

4. The disclosure is objected to because of the following informalities: Paragraph [0029] refers Figure 10 and "biologic fluid 34". However, in Figure 10 no label "34" is present, it is assumed that "34" is a typo and "54" is the number that should have been used.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3, 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Austin et al. (U.S. Patent No. 6,632,652), hereinafter referred to as "Austin"

In regards to claim 1, Austin teaches an apparatus (80) comprising a first planar member (26), a second planar member (88), wherein at least on the first planar member and second planar member is transparent, at least three separators (62) disposed between the planar members, each separator individually having a height and the separators collectively having a mean height, and wherein at least one of the first planar member, second planar member, or separators is sufficiently deformable (see column 9 lines 29-67, column 10 lines 1-22, and Fig. 7).

In regards to claim 2, Austin teaches an apparatus wherein at least one of the first planar member and second planar member comprises flexible plastic (see column 10 lines 1-15)

In regards to claim 3, Austin teaches an apparatus wherein both of the planar members comprise flexible plastic (see column 10 lines 1-15 and column 7 lines 44-49).

In regards to claim 7, Austin teaches an apparatus (80) wherein the separators (62) are attached to at least one of the first planar member (26) or second planar member (88) (see column 9 lines 66-67, column 10 lines 1-5 and Fig. 7).

In regards to claim 11, Austin teaches that the separators are projections of uniform height (see column 9 lines 46-53 and column 4 lines 18-40 and Figs. 2-4).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
9. Claims 4-6 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Austin.

10. In regards to claim 4, Austin teaches the apparatus as described above.

Austin does not specifically teach an apparatus wherein the separators are deformable relative to the first planar member and the second planar member.

11. However, Austin does teach a second planar member (88) made of materials such as silicon, quartz, sapphire, or even an elastomer. Austin also teaches that the first planar member (26) is formed using an elastomer (see column 7 lines 44-53). The separators, which are made of an elastomer would be more deformable than a very rigid

material such as silicon. Furthermore, the separators being very small projections made of the same material as the first planar member (26) would have greater deformability than the large base. So, the separators would be deformable relative to the planar members

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include separators that are deformable relative to the first and second planar members for the benefit of creating a seal between the planar members and the separators.

In regards to claims 5 and 6, Austin teaches the apparatus as described above. Austin does not specifically teach an apparatus wherein the separators are deformable relative to the first planar member and the second planar member, or that the first planar member has greater deformability relative to the second planar member and the separators.

However, Austin does teach a second planar member (88) made of materials such as silicon, quartz, sapphire, or even an elastomer. Austin also teaches that the first planar member (26) is formed using an elastomer (see column 7 lines 44-53). The separators, being made of elastomer, would have greater deformability than the second planar member which is made of a rigid material such as silicon or quartz. Furthermore, the separators being very small projections made of the same material as the first planar member (26) would have greater deformability than a base (26). Also, the base could be made sufficiently thin so that it is more deformable relative to the separators. So, one of the separators, first planar member, and second planar member,

would have greater deformability relative to at least one of the others for the benefit of creating a seal between the planar members and the separators. Furthermore, the first planar member would have greater deformability than the second planar member and the separators.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include a first planar member, a second planar member, or separators that have greater deformability relative to one of the others, or to include a first planar member that has greater deformability than the second planar member and the separators for the benefit of creating a seal between the planar members and the separators.

In regards to claim 33, Austin teaches an apparatus (80) comprising a first planar member (26), a second planar member (88), wherein at least on the first planar member and second planar member is transparent, at least three separators (62) disposed between the planar members, each separator individually having a height and the separators collectively having a mean height (see column 9 lines 29-67, column 10 lines 1-22, and Fig. 7).

Austin does not specifically teach an apparatus wherein at least one of the first planar member, second planar member, or separators is sufficiently deformable to permit the chamber height to be substantially unaffected by the presence of debris. However, Austin does teach an apparatus made of elastomers (see column 7 lines 44-53). Elastomers are known in the art to have large amounts of deformability. So, the

thinner cover slide made of an elastic material would be sufficiently deformable to be unaffected by the presence of debris

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a first planar member, second planar member or separators that are sufficiently deformable to be substantially unaffected by the presence of debris for the benefit of creating a seal between the planar members and the separators.

12. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Austin as applied above in view of Bisconte (U.S. Patent No. 4,883,642), hereinafter referred to as "Bisconte".

Austin teaches the apparatus as described above, however Austin does not teach an apparatus wherein at least one of the first planar member or second planar member comprises linked rigid elements.

In the analogous art of holding, treating, storing and analyzing fixed or living biological samples automatically or continuously Bisconte teaches an apparatus with a first planar member (ribbon 1a) and second planar member (film 21) wherein one of the first planar or the second planar member comprises linked rigid elements (longitudinally extending biological storage zones) and the other of the first planar member or second planar member comprises flexible plastic (see column 9 lines 29-35, column 10 lines 61-68, and Figs 5a and 5b). This is for the benefit of separating different wells for the continuous processing of biological samples.

Therefore it would have been obvious to one of ordinary skill at the time of the invention to include the linked rigid elements in the Austin apparatus in view of Bisconte for the benefit of creating separate biological chambers.

13. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Austin as applied above in view of Vermeiden et al. (U.S. Patent No. 6,551,554), hereinafter referred to a "Vermeiden".

Austin teaches the apparatus as described above and teaches the use of a dye to allow for the visualization of blood cells (see column 13 lines 35-42), however Austin does not teach separators that a slightly compressible plastic beads.

In the analogous art of counting microscopic particles in a liquid medium, Vermeiden teaches the use of plastic beads for the benefit of creating the depth of the counting compartment (see column 1 lines 45-50).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Austin apparatus in view of Vermeiden to include plastic beads as the separation medium for the benefit of creating separation between the two plates.

14. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Austin as applied above in view of Böhm (U.S. Patent No. 7,179,423), hereinafter referred to as "Böhm".

Austin teaches the apparatus as described above, however, Austin does not teach an apparatus wherein one of the first planar member or second planar member comprises one or more ports.

In the analogous art of microscale fluid handling, Böhm teaches an apparatus with a first and second member with one of the members comprising a port (17) (see column 12 lines 4-23 and Fig. 2b) for the benefit of allowing fluid enter the testing region and for the benefit of performing large numbers of chemical operations in a highly parallel fashion (see column 1 lines 36-40) and for the benefit of significantly reducing the amount of liquid sample needed (see column 10 lines 43-46).

Therefore, it would have been obvious to one of ordinary skill at the time of the invention to modify the Austin invention in view of Böhm to include ports for the benefit of allowing fluid to enter the testing and area and for the benefit of performing large numbers of chemical operations quickly and reducing the amount of liquid volume needed for them.

Conclusion

Claims 13-32 are restricted and claims 1-12 and 33 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles D. Hammond whose telephone number is (571)270-3595. The examiner can normally be reached on Monday-Friday 8:00am-4:30pm est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ortiz Angela can be reached on (571)272-1206. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CDH

/Angela Ortiz/

Supervisory Patent Examiner, Art Unit 4172